

Questions And Answers For The European Union Requirements

II. FACILITY, EQUIPMENT, PROCEDURES

1. Does packaging material have to be shrink wrapped when received and while in storage?

There is no specific requirement for shrink wrapping, however, the packaging material must be stored and handled in a sanitary manner. A plant may choose to shrink wrap as an aid to sanitary storage and handling.

2. Is cove molding required under the new agreement?

No. Neither cove molding nor the 45 degree slope will be required. However, the wall and floor junctions, as well as the cracks, must be properly sealed to maintain sanitary conditions.

3. Do the wall and floor junction requirements of II.B. apply to all rooms of the plant?

No. This requirement only applies to rooms where product is being produced, handled, or stored.

4. Does packaging material for EU destined product have to be stored separately from packaging material used for products destined for other markets?

No. EU packaging material does not have to be stored separately. It can be stored in the same room as other packaging material.

5. When must the plant phase out the use of wooden pallets?

There is no specific deadline for the phase out of wooden pallets, however this should be a goal of all establishments shipping to the EU.

6. If plastic slip sheets are used on wooden pallets, does the 3 meter rule apply?

Yes.

7. Will there be any flexibility offered with regards to the 3-meter rule?

No. This 3-meter rule was a compromise with respect to the use of wooden pallets. The EU would ideally like plants to use only plastic pallets. The best agreement reached was that wooden pallets would be phased out over time, but until then, the 3-meter rule will apply.

8. Would it be acceptable to completely enclose the pallet in plastic?

The top must be covered. If a plant chooses to go beyond this requirement, it must be done in a sanitary manner.

9. Can packaging materials be stored on wooden pallets without a plastic slip sheet?

Yes. The plastic slip sheet requirement only applies to exposed product areas.

10. Must cleaning and other materials be stored separately from packaging materials?

Yes.

11. Can product in combo bins be stored in coolers or freezers with boxed product?

Yes, if the combo is covered with a lid or the plastic combo liner is closed over the product.

12. Is sterilization the correct term in II.K.?

A better term to use is "sanitization". However the key to compliance is using water of the correct temperature.

13. Do sanitizers have to have an overflow mechanism?

No. Sanitizers must be maintained and used according to FSIS requirements. Overflows can be an option for a plant to maintain sanitizers in an acceptable manner.

14. Are the sterilization (sanitization) procedures for utensils and implements applicable only when handling raw meat?

No. These procedures are to be used in handling any meat/poultry product eligible for export to the EU.

15. Will the "washing" of meat dropped on the floor be permitted?

FSIS regulations will apply in this situation.

16. Previously, we could not pack offal products in same room as other products being packed. Is this an acceptable practice now?

Yes. However, edible and inedible product cannot be packed in the same room. Also, packed product may not be stored in coolers with exposed product.

III. EMPLOYEE MEDICAL CERTIFICATION

1. What kinds of medical records must be available to the auditors?

The medical certification statements must be available. The actual medical examination records are not required to be available.

2. How does the reviewer know that a physician's assistant or a registered nurse is under the supervision of medical doctor?

The establishment must be able to demonstrate this.

3. What needs to be included in the medical examination?

These requirements are left to the discretion of the medical official signing the certification statement. The EU does not mandate specific disease testing (e.g. hepatitis, tuberculosis, etc.) Specific disease testing is left up to the professional judgement of the medical professional that is signing the certification.

IV. WATER TESTING

1. Must you maintain the EU water and residue testing programs even if you are not currently exporting to the EU?

Yes. This is part of the plant approval process.

2. Why does the EU insist on continuing the water and residue testing programs?

These issues are still being discussed with the EU delegation. However, in the interim, the programs, as outlined in the requirements will continue.

3. If our water testing program is currently approved for the EU, must we get this program reapproved?

No. FSIS water potability requirements currently are not an acceptable alternative to EU water testing requirements.

4. What is permissible as acceptable chlorination levels in water?

The levels acceptable under FSIS regulations for potable water.

V. ANTEMORTEM INSPECTION

1. Are there any additional requirements for antemortem inspection of poultry?

No. FSIS requirements apply.

VI. SWINE HEART INCISION

1. Are 6 swine hearts required to be incised and examined each week even though the establishment may not be producing for export to the EU?

Yes. If an establishment is on the approved plant list, the hearts must be examined.

2. How is swine heart incision affected if a plant does not slaughter for some period of time during the year?

Each approved establishment must incise and examine 300 hearts per year. The 6 hearts per week requirement is based on the plant operating on a continuous basis. The number of hearts per week should be increased to assure that 300 are examined annually if the plant does not slaughter on a weekly basis.

3. Who can perform the heart inspection?

The inspection must be done by an FSIS VMO. It may be done by the IIC VMO, the antemortem VMO or by a circuit supervisor VMO.

VII. TRICHINAE TREATMENT

1. With respect to trichinae treatment, are processed products subject to EU requirements?

Processed products containing pork must be produced from raw pork meat that complies with the EU requirements, including trichinae treatment.*

2. Will the EU approve trichinae testing labs?

EU directive 77/96/EEC provides the methodology for trichinae testing. AMS provides analyst training and certification that the laboratory complies with the testing methodology indicated in this directive. The EU does not provide individual laboratory certification. *

VIII. ANTIMICROBIAL TREATMENT

1. Will it be acceptable to “turn off” or discontinue the use of an antimicrobial rinse for product being prepared for domestic commerce when moving into an EU mode of production?

Yes, provided the action is effective in preventing product contact of the antimicrobial rinse.

IX. POULTRY CHILLING

1. Is the selection and testing of poultry carcasses and subsequent report of the assessment and results to Export Staff /Technical Service Center optional when an establishment chooses to use an alternative chilling system as outlined in IX.B.?

No. The establishment must select, test, and report to use an alternative system.

2. Will the EU have to validate alternative chilling systems?

No. FSIS will do the validation.

3. Is the alternative chilling system option a complete substitute for IX.A.?

Yes. None of the requirements in IX.A. apply, if the establishment complies with the requirements of IX.B.

4. Is there a specific time for chilling poultry to 40°F?

There are no special chill-time requirements for EU, but poultry must reach 40°F in the shortest time possible after slaughter and at least meet FSIS requirements according to 381.66.

5. Can poultry carcasses be hot deboned?

Carcasses weighing up to 6 lb. that begin the chilling process must reach 40°F before they can be deboned. Carcasses that weigh more than 6 lb can be hot deboned in accordance with FSIS regulations.

X. RESIDUE TESTING

1. Is there a residue testing requirement for poultry?

FSIS is currently evaluating the EU residue-testing requirements for poultry against the compounds tested for in the FSIS National Residue Testing Program. Any additional requirements will be reflected in the EU Requirements.

2. Will the EU "Member States" be allowed to residue-sample U.S. product when it enters their country as they sometimes do now?

Yes. As we do in the U.S., monitoring samples for residue testing can be sampled by the member states at port of entry.

3. Are further processors subject to maintaining a Residue Testing Program?

No. Only slaughter plants. Processors will receive EU product in containers sealed by the oval health label. When this label is broken and the product further processed, the processor will reapply their own oval health label prior to exporting the product to the EU. Also, keep in mind, combo bins may be used to move EU destined product from one plant to another within the U.S., but are not acceptable to use in exporting product to the EU.

4. Is a Residue Testing Program required for beef exports?

Yes. Red meat slaughter plants need to participate in the AMS residue Residue Testing Program, separate from the Export Applications. Also, if plants change labs, it's their responsibility to notify the Export Staff at the Technical Service Center.

XI. NON-HORMONE TREATED BEEF AND VEAL

1. What does HFC mean?

Hormone Free Cattle

2. What does NHTC mean?

Non-Hormone Treated Cattle

XII. SOURCE OF RAW MATERIAL

1. Are only U.S. slaughter plants that are EU approved eligible to supply raw materials to U.S. processing plants or can raw materials be obtained from any EU approved plant worldwide?

Raw material may be imported for the purpose of EU production provided it bears the EU Health mark, as described in the EU Requirements, and is eligible for importation into the United States.

XIV. FINLAND AND SWEDEN

1. Can the additional requirements of Sweden/Finland be included in the export library?

Yes. This information will be added.

XV. FSIS OVERSIGHT

1. Is there a requirement for veterinary supervision of processing plants and cold storages?

No. FSIS domestic requirements apply.

XVII. PLANT APPROVAL PROCESS

1. Do processing plants have to meet these requirements?

Yes. All slaughter, processing and cold storage establishments must meet these requirements.

2. Is the completion of FSIS 9080-3, Establishment application for Export, mandatory for those establishments seeking EU approval?

Yes.

3. Do establishments currently on the EU approved establishment list or on EU member country lists have to reapply?

Yes. These plants must submit FSIS 9080-3.

4. Please expand upon "deficiencies" with respect to gaining a "partial" versus "full" plant approval. For example, if a plant applies for "full" approval, but are found deficient in a certain area, can that plant receive "partial" approval?

Yes. If a plant applies for "full" approval, and deficiencies are found that would prohibit granting a "full" approval, then depending on what the deficiencies are that are found, a "partial" approval may or may not be permissible. Remember, a plant will be reviewed based on the information provided on the Application for Export. Following the review, the plant will be advised regarding any deficiencies and whether or not a "partial" approval would be permissible.

5. If the slaughter operation is approved but the processing operation is not, can I request a "partial" approval?

Yes. This will be discussed at the time of the exit interview.

6. Why is there a "rendering" check-off block on the FSIS Form 9080-3?

This form will be used for all countries requiring plant approval, not just for the EU.

7. Since industry will be charged for these reviews, can industry transport the government reviewers on corporate jets?

No.

8. How long will it take for EU confirmation to allow plants to begin exporting?

Once FSIS certification is submitted, the EU has a 21-day approval period for new plants.

9. Will plants still be subject to EU "Member State" requirements?

No. This agreement is a harmonized animal and public health plan. There will be no additional animal and public health requirements imposed by the "Member States".

10. Who will maintain the EU Approved Plant List?

FSIS will submit recommendations, and maintain the List.

11. Can we select the reviewers?

No.

12. Does the EU have to review US plants prior to approval?

No. FSIS will review the facility prior to certifying the plant to the EU to assure compliance with EU requirements. The EU will then approve plants based on the information provided by FSIS. Further, the EU will carry out verification procedures, which may include an audit of a plant that has been approved.